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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/774,555	01/31/2001	Mitchell Anthony Delong	7996	4966

27752 7590 07/09/2002

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[REDACTED] EXAMINER

BADIO, BARBARA P

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1616

DATE MAILED: 07/09/2002

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/774,555	DELONG ET AL.
	Examiner	Art Unit
	Barbara P Badio, Ph.D.	1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 22-44 is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 1-21 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on ____ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. ____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>1 and 3</u> . | 6) <input type="checkbox"/> Other: _____ |

First Office Action on the Merits

Election/Restrictions

1. Claims 22-44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 4.

2. Based on applicant's election of species, claims 7, 9, 10 and 12 stand withdrawn from further consideration as being drawn to a nonelected species.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

W A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-6, 8, 11 and 13-21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 09/774,557. Although the conflicting claims are not

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identical, they are not patentably distinct from each other because the claims are drawn to compositions comprising similar prostaglandin analogs.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

W) 6. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claim recites "component C)" but is dependent on claim 1 which does not recite or define "component C". Therefore, the ordinary artisan would be unable to determine the metes and bound of the claimed invention.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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8. Claims 1-6, 8, 11, 13-17 and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Wos et al. (WO99/12895).

Wos et al. teach a generic group of prostaglandin F analogs useful as FP agonists such as 13,14-dihydro-16-(phenylthio) tetranor Prostaglandin $F_{1\alpha}$ methyl ester (see the entire article, especially examples 1-22). The reference teaches various carriers including talc, polyethylene glycol, water and glycerin (see page 32, paragraph 1, lines 1-11); various routes of administration including topical application (see page 32, paragraph 5, lines 1-2 and page 32, paragraph 6, lines 1-3; especially page 34, Example C) and dosage range of the compound for administration (see page 33, paragraphs 4 and 5). The composition taught by the reference is encompassed by the instant claims.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-6, 8, 11 and 13-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wos et al. (WO99/12895).

Wos et al. teach a generic group of prostaglandin F analogs useful as FP agonists such as 13,14-dihydro-16-(phenylthio) tetranor Prostaglandin $F_{1\alpha}$ methyl ester

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(see the entire article, especially examples 1-22). The reference teaches various carriers including talc, polyethylene glycol, water and glycerin (see page 32, paragraph 1, lines 1-11); various routes of administration including topical application (see page 32, paragraph 5, lines 1-2 and page 32, paragraph 6, lines 1-3; especially page 34, Example C) and dosage range of the compound for administration (see page 33, paragraphs 4 and 5).

The instant claims differ from the reference by reciting additional compounds not exemplified by Wos. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to make any of the species of prostaglandin F analogs of the genus taught by Wos, including those of the instant claims, with the reasonable expectation that any of the species of the genus would have similar properties, and, thus the same use as the genus as a whole. The motivation is based on the desire to make additional compounds useful as FP agonists as taught by the reference.

Claim 18 further differ from the reference by reciting specific propellants known in the art. However, the formulation of topical preparations and the combination of various excipients, including propellants are within the level of skill of the ordinary artisan in the pharmaceutical art. Thus, the utilization of the specific propellants recited by the instant claim would be obvious to the skilled artisan.

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Telephone Inquiry

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Barbara Badio
Barbara P Badio, Ph.D.
Primary Examiner
Art Unit 1616

BB
July 9, 2002